UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,067	08/16/2001	David B. Weiner	UPN-3695	4038

34136 7590 08/08/2003

COZEN O'CONNOR, P.C.
1900 MARKET STREET
PHILADELPHIA, PA 19103-3508

EXAMINER	
SHUKLA, RAM R	

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 08/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,067	WEINER ET AL.	
	Examiner	Art Unit	
	Ram R. Shukla	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicants' response and amendments filed 6-25-03 have been entered.

2. Claims 1-31 are pending.

3. Applicants' arguments that making the office action of 3-27-03 a Final rejection was premature because new grounds of rejection were presented have been found persuasive and the finality of the office action of 3-27-03 has been withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3, 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an in vitro method of delivering a protein to a macrophage cell or a cell of macrophage derived lineage, does not reasonably provide enablement for an in vivo method for reasons of record set forth in the previous office action of 3-27-03. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 9-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office action of 3-27-03. It is noted that while claims 30 and 31 were left out of the enablement rejection, since claim 25 is rejected on which these claims are rejected, claims 30 and 31 would be rejected for same reasons.

Response to Arguments

Applicant's arguments filed 6-25-03 have been fully considered but they are not persuasive. Regarding the issue, "Figure 7 is a diagrammatic representation of a plasmid called pNeZCD3alpah.1, however, it is not clear as to what encoding sequence was used in this vector" applicants have argued that specific DNA molecule is not limited. These arguments are not persuasive because the figure recites a particular plasmid and for an artisan to make that plasmid artisan will require what the coding sequence is, even though different fragments could be cloned in the plasmid. Regarding, the issue, "the specification does not provide any specific guidance or structure of these promoters, what sequences will be required for the promoter function etc. In other words, an artisan would not know, what parts of the promoter or what parts of the regulatory sequences to use in making an expression vector. The specification does not provide any specific guidance as to what amount of plasmids or vectors will be administered, rather the specification does not provide any specific guidance to practice the claimed method. Therefore, an artisan of skill would have depended on the art for practicing the claimed methods and as discussed below the art of in vivo gene delivery and gene therapy is unpredictable, particularly vector construction and design. It is noted that claims are also directed to administration of a vector to lymph nodes at any site so that the vector is administered to the lymph nodes, however, the specification does not teach any specific description of where and how the administration will be carried out. It is pointed out that while the claimed invention recites macrophage specific promoters, one major issue is what vector will be used such that the administration to a subject was effective and was able to deliver the vector to macrophages. The specification does not provide any specific teachings as to what vectors will be suitable for this specific purpose" except for argument, applicants did not provide any evidence as to where was the guidance discussed above provided in the specification. Applicants argument alone cannot take place of evidence lacking in the record (see In re Scarbrough 182 USPQ, (CCPA) 1979).

Regarding the arts of Crystal, Anderson, Clark and other arts that review the state of the art of gene therapy and vector targeting, applicants have not provided any guidance or evidence as to how the known limitations in the art will be dealt by an artisan. While the claims do not recite treating a disease, that is the intent of the claimed method. It is noted that while limitations appearing in the specification cannot be read into the claims, claims have to be enabled for the intended use. Applicants' arguments that data provided is sufficient for drug approval by FDA are irrelevant because the issue here is patentability and not drug approval.

Claim Rejections - 35 USC § 102

The 102 rejection of claims 1-3 and 5-7 has been withdrawn in view of applicants arguments.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malik et al in view of Dropulic et al (US Patent 5,888,767, March 30, 1999, effective filing date 11-28-1996), Kataoka et al (Journal of Biological Chemistry 272:18209-18215, 1997) and Horvai et al (Proc. Natl. Acad. Sci. 92:5591-5393, 1995) for reasons of record set forth in the previous office action of 3-27-03.

Response to Arguments

Applicant's arguments filed 6-25-03 have been fully considered but they are not persuasive. Applicants have argued that none of the cited arts teach administration of DNA to a site in an individual. These arguments are not persuasive because the patent by Dropulic et al teaches this. The claims of Dropulic et al are drawn to administration to a host cell and encompass both in vivo and in vitro. Additionally, they teach contacting with a HIV vector which is a DNA or delivering a vector to an individual and discuss different modes of administration (see columns 24-28). They define what a vector in and that macrophage is a target. It is noted that in the instantly pending case, the claim does not exclude a viral vector. Cited arts of Malik et al and Horvai et al Kataoka et al teach why a vector with hematopoietic cell promoter is useful for gene therapy. In other words, an artisan of skill at the time of the invention knew that using macrophage specific promoter or CD11b promoter or scavenger receptor promoter, one could target gene expression to macrophages. Therefore, At the time of the invention, it would have been obvious to an artisan of ordinary skill to modify the vectors of Malik et al by substituting the promoters of CD156 gene, scavenger receptor gene or any other macrophage cell specific promoters with a reasonable expectation of success and administer the vector to an individual for delivering a gene of interest to macrophages. An artisan of skill would have motivated to modify the vector to find the best promoter that will allow specific expression in macrophages and could be used for delivering genes to atherosclerotic tissues or cells. In fact, Horvai et al clearly state in their abstract "The ability of scavenger receptor promoter and enhancer to target gene expression to macrophages in vivo, including foam cells of atherosclerotic lesions, suggests that these regulatory elements will be of general utility in the study of macrophage differentiation and function by permitting specific modifications of macrophage gene expression". Similar conclusion was drawn by Malik (see the last sentence in the discussion section).Additionally, an artisan could modify the vector for making conditional vectors for expressing toxins as taught by Dropulic et al.

8. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. The after-final fax number is (703) 87209307. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.

RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632